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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,322	11/12/2003	Enrique Carlos Leira	60004310-0023	6487
33436 7590 09/02/2008 SAINT LOUIS UNIVERSITY OFFICE OF INNOVATION AND INTELLECTUAL PROPERTY 3556 CAROLINE MALL SUITE C208 ST. LOUIS, MO 63104				
EXAMINER				
GRAY, PHILLIP A				
ART UNIT		PAPER NUMBER		
3767				
MAIL DATE		DELIVERY MODE		
09/02/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/706,322

Applicant(s)

LEIRA ET AL.

Examiner

Phillip Gray

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to applicant's communication of 5/27/2008.
Currently claims 1-41 are pending and rejected below.

Response to Arguments

Applicant's arguments filed 5/27/2008 have been fully considered but they are not persuasive. It is examiners position that the prior art, particularly the Duffy reference does satisfy and teach the newly amended claim limitations of "an inlet on one side of the rod", an outlet "on an opposite side of the rod", and the fluid channel "is generally straight across a cross section of the rod". During examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). It is examiners position that the applicant has not completely or fully identified which side is which, but rather that the inlet and outlet are on opposite sides of the rod. Comparing figure 3 of Duffy with the applicants figure 1 and figure 1A, examiner is of the position that the inlet of Duffy teaches that it is on an opposite "proximal" side then the "distal" outlet side of the rod. Concerning the fluid channel, it is examiners position that as in figure 3 of Duffy the fluid flow path is "generally straight" and is "across a cross-section of the rod" (note path of fluid flow through the rod).

The elements disclosed in Duffy are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7,13,16-22,24, 27, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy (U.S. Patent Number 6,050,973) in view of Cole (U.S. 934,286).

Duffy discloses an automatic flow control device, method, and kit, which is used for collecting a fluid comprising a pressure sensitive valve (as in figure 2 through 4).

The Duffy device valve comprises a housing (30,80) and inlet (near 36), an outlet (near 66 with affixed tubing 37), a fluid channel (76), and a cylinder shaped rod (70) which can completely obstruct the communication between the inlet and outlet such that when a pressure differential between the inlet and the outlet is at or greater than a preset value, the rod is displaced to obstruct the fluid from flowing from the inlet to the outlet and when the pressure differential between the inlet and the outlet is less than the preset value, the rod is not displaced to allow the fluid to flow from the inlet to the outlet, and valves (see abstract, and paragraphs at columns 4 line 25 through column 5 line 20). This rod is connected to the outlet by a spring (84) and retaining pin (82 for example). Further the Duffy rod is perpendicular to the fluid channel (as the fluid enters opening 37) or inline (near 76 and opening 36), has a constriction opening (aperture on rod near 76) and a rod channel contiguous with the fluid channel (see figures 1-4).

Cole discloses a valve for use in fluid drainage that comprises a housing (5), housing inlet (13) and outlet (near 11), fluid channel (path which fluid would flow through as in figure 2), a rod (8/9) that can be in only two positions, a first position (figure 3) and a second position (figure 2), wherein the rod has a "rod fluid channel inlet" (10), rod fluid channel" (hollow space of the rod), and "rod fluid channel outlet" (end of rod near 9), which are generally inline and the fluid flow is generally straight, Further the only one of two positions of the rod is readily visible to an operator during the operation of the device (figure 3)

Duffy discloses the claimed invention except for the generally inline and straight rod fluid channel. Cole teaches that it is known to use the generally inline and straight

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rod fluid channel as set forth in paragraphs at Lines 8-74 to provide a valve which is "simple in structure, reliable in operation and which can be readily connected up anywhere on the line". It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Duffy with the generally inline and straight rod fluid channel as taught by Cole, since such a modification would provide the system with a generally inline and straight rod fluid channel for providing a valve "automatic in operation, it is simple in construction and therefore not liable to get out of order, and it effectually serves the purpose for which it is designed.

Further concerning the amendments to the claims of "the valve can be in only one of two positions", a first completely obstructing position and a second position with a non displaced rod and unrestricted flow from inlet to outlet, it is examiners position that Duffy discloses such an operation (see abstract, and paragraphs at columns 4 line 25 through column 5 line 20 and "first position" in figure 2 and "second position" in figure 4). The elements disclosed in Duffy are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper.

Claims 8-11, 12, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy in view of Cole.

Concerning claims 8-11, Duffy in view of Cole discloses the claimed invention except for the preset value is at or greater than 10 mm of H₂O, 50 mm of H₂O, 100mm

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of H₂O, or between 179mm and 221mm of H₂O. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a preset value is at or greater than 10 mm of H₂O, 50 mm of H₂O, 100mm of H₂O, or between 179mm and 221mm of H₂O, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

Concerning claims 12 and 23, Duffy in view of Cole discloses the claimed invention except for the fluid comprising body fluid, blood, or CSF. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the fluid be body fluid, blood, or CSF, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 14,15, 25, 26, and 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy in view of Cole in further view of Bierman (U.S. Patent Number 2,535,998).

Duffy in view of Cole discloses the claimed invention except for the stopcock, threeway valve, needle and manometer assembly is affixed to the outlet from the housing. Bierman teaches that it is known to use a stopcock, threeway valve, needle and manometer assembly is affixed to the outlet from the housing as set forth in

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paragraphs at columns 1-3 to provide an ability for the pulse to be observed and control fluid flow by stopping. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the flow control system as taught by Duffy in view of Cole with the stopcock, threeway valve, needle and manometer assembly is affixed to the outlet from the housing as taught by Bierman, since such a modification would provide the flow control system with a stopcock, threeway valve, needle and manometer assembly is affixed to the outlet from the housing for providing an ability for the pulse to be observed and control fluid flow by stopping.

Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy in view of Cole. Duffy in view of Cole discloses the claimed invention except for the housing being a sterile transparent material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to cause the housing to be a sterile transparent material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). and it would be advantageous to be able to view the contents directly as the flow through the valve and housing.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/

Examiner, Art Unit 3767

/Kevin C. Simmons/

Supervisory Patent Examiner, Art Unit 3767